

REMARKS

Claims 1-26 are currently pending. In the Office Action mailed March 27, 2008 (“Office Action”) claims 1-26 were rejected. Through this amendment claim 1 is amended to define more particularly the subject matter sought to be patented, without prejudice to pursue the original subject matter, for example, in a continuation application. No new subject matter has been added. Applicants respectfully request reconsideration and allowance of the claims in light of these remarks.

Claim Objections

On page 2 of the Office Action, claims 14 and 18 were objected to. According to the Examiner, the term “said onset electrical stimulus level” found in both claims 14 and 18 lacks antecedent basis. The Applicants respectfully traverse. The term “said onset electrical stimulus level” finds antecedent basis in the last two lines of claim 1 which state, “communicating to a surgeon operating on the patient’s spine **an onset electrical stimulus level** which causes said onset neuro-muscular response.” The term “said onset electrical stimulus level” in claims 14 and 18 refers back to this term found in claim 1 and finds proper antecedent basis there. Applicants believe the objection is overcome and respectfully request an indication to that effect.

Claim Rejections

35 USC 103(a)

Claims 1-13, 24 and 25 were rejected under 35 USC 103(a) as being unpatentable over US Patent 5,474,558 to Neubardt (“Neubardt”) in view of Calancie et al.’s article entitled “Stimulus-Evoked EMG Monitoring During Transpedicular Lumbosacral Spine Instrumentation” (“Calancie”). The Applicants respectfully traverse this rejection as follows.

To establish a *prima facie* case of obviousness under 35 USC § 103(a) in view of a reference or combination of references, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art

reference(s) must teach or suggest all the claim limitations. In the absence of one or more of these criteria a rejection for obviousness is inappropriate and cannot stand.

Claim 1, as amended, recites a method of determining structural integrity of a bone within the spine of a patient using a neurophysiology system. The bone has a first aspect and a second aspect. The second aspect is separated from the first aspect by a width and is located adjacent to a spinal nerve. The method comprises the following steps. Applying an electrical stimulus to the first aspect of the bone. Electrically monitoring a muscle myotome associated with the spinal nerve. *Automatically determining an onset neuro-muscular response* to the application of said electrical stimulus to said first aspect of said bone by *automatically increasing the electrical stimulus* until the onset neuro-muscular response is detected, wherein the *automatic increasing is controlled by the neurophysiology system*. And finally, communicating to a surgeon operating on the patient's spine *an onset electrical stimulus level* which causes said onset neuro-muscular response.

As discussed in prior submissions, the present invention advantageously automates the process of pedicle integrity testing by automatically determining an onset neuromuscular response to an electrical stimulus and communicating to a surgeon the onset electrical stimulus level that causes the onset neuromuscular response. While Neubardt and Calancie are certainly relevant to performing pedicle integrity assessments associated with pedicle screw placement, both employ traditional screw test methods that fail to disclose or suggest at least the claimed feature of “*automatically determining an onset neuro -muscular response* to the application of said electrical stimulus to said first aspect of said bone *by automatically increasing said electrical stimulus until said onset neuro-muscular response is detected, wherein the automatic increasing is controlled by said neurophysiology system*” The Examiner expressly acknowledges the failure of Neubardt to teach these elements on page 3 of the Office Action.

Calancie does not cure the deficiencies noted by the Examiner in Neubardt. Calancie does not automatically determine the onset neuro-muscular response by *automatically* increasing the electrical stimulus until the onset neuron-muscular response is detected, wherein the *automatic increasing is controlled by the neurophysiology system*.” Rather, in Calancie any increase in electrical stimulus occurs **manually** and is controlled by the neurophysiologist. See

page 2781, Col 2, lines 13-15 in Calancie. In the “Response to Arguments” section beginning on Page 8 of the Office Action, it was asserted that the steps of “automatically determining” the onset response and “automatically increasing” the stimulus were taught by Calancie because a person of skill in the art could determine that these steps are performed because the neurophysiologist, and the mere act of performing the steps makes the performance “automatic”. The Applicants respectfully disagree with this assertion, but have nevertheless amended claim 1 to express that the “*automatic increasing is controlled by said neurophysiology system.*” Applicants expressly reserve the right to maintain argument in the future that Calancie fails to disclose “automatically determining an onset neuro -muscular response” and “automatically increasing said electrical stimulus until said onset neuro-muscular response is detected.”

With Neubardt and Calancie being silent regarding the above-identified features of claim 1, Applicants respectfully submit that these references, whether taken alone or in combination, fail to contain the requisite teaching or suggestion that would have led one of ordinary skill in the art to the present invention as set forth in amended claim 1. Claim 1 is believed to be in proper condition for allowance and an indication of such is hereby respectfully requested. Claims 2-13 and 24-25, being dependent upon and further limiting independent claim 1, should be allowable for the reasons set forth in support of the allowability of claim 1, as well as the additional limitations they contain.

The remaining claims were rejected under 35 USC 103 as being obvious over Neubardt and Calancie and further in view of one of the Hacker (US 6,334,068), Raymond (US 5,284,153), and Neurovision SE Nerve Locator/Monitor references. As set forth above, Neubardt and Calancie fail to teach features of independent claim 1. The Applicants assert that these additional references do not cure the voids found in the combination of Neubardt and Calancie. As such, whether taken alone or in combination, the cited art do not appear to contain any requisite teaching, suggestion or motivation that would have lead someone of ordinary skill in the art to the present invention now claimed. Allowance of all currently pending claims is hereby earnestly solicited.

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or

concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

Conclusion

Favorable consideration and allowance of the claims are respectfully requested. Applicants hereby authorize a fee payment of \$525.00 for a three month extension of time request from Deposit Account No.: 50-2040 for Customer No.: 30,328. No other fees are believed to be due at this, however, in the event that there are any additional fees to be charged or payments to be credited, the Applicants hereby request they be made to the deposit account listed above. In the event that there are any questions concerning this Response to Office Action or the application in general, the Examiner is cordially invited to telephone the undersigned attorney so that prosecution may be expedited.

Respectfully submitted,
NUVASIVE, INC.

/roryschermerhorn/
By: _____
Rory Schermerhorn, Esq.
Registration No. 58,148

7475 Lusk Boulevard
San Diego, CA 92121
Tel.: (858) 909-1845

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